DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANNUAL REPORT

OF THE

BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE

for the period

October 1, 2000 though September 30, 2001

FUNCTION

The Committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of biological response modifiers that are intended for use in the prevention and treatment of a broad spectrum of human diseases. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met three times during the reporting period. Meetings were held in Bethesda, Maryland.

The dates of those meetings were: November 16-17, 2000, April 5-6, 2001, and July 13, 2001.

The meeting on April 5-6, 2001 included a closed session to permit discussion of matters of a personal nature.

ACCOMPLISHMENTS

At the November 16-17, 2002 meeting:

In open session, the Biological Response Modifiers Advisory Committee discussed and made recommendations regarding issues related to gene therapy clinical trials including preclinical models, product characterization, and long-term follow-up.

At the April 5-6, 2001 meeting:

In open session, the Committee reviewed and discussed responses to a letter that was sent to all IND gene therapy holders requesting submission of information on pre-clinical and clinical issues, product characterization, and quality control.

The Committee also heard the results from several clinical site inspections where gene therapy clinical trials are being conducted.

The Committee discussed the feasibility of implementing CBER's plan for long-term follow up of gene therapy patients.

The Committee also heard the announcement of the proposed rule on "Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Human Gene Therapy or Xenotransplantation". This rule has been published in the Federal Register.

The Committee heard an update of the research programs in the Division of Monoclonal Antibodies and the Division of Cellular and Gene Therapies.

In closed session, the Committee recommended personnel and program actions for the Laboratory of Molecular and Developmental Immunology, Division of Monoclonal Antibodies; and the Laboratory of Molecular and Tumor Biology, Division of Cellular and Gene Therapies. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review.

At the July 13, 2001 meeting:

In open session, the Committee discussed updates on safety testing of adenovirus vectors and responses to the March 6, 2000 FDA Gene Therapy Letter related to adenovirus vector titer measurements and replication competent adenovirus levels.

Nov 16, 2001
Date

Gail M. Dapolito
Gail M. Dapolito
Executive Secretary

BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
FOOD AND DRUG ADMINISTRATION

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANNUAL REPORT

OF THE

BLOOD PRODUCTS ADVISORY COMMITTEE

for the period

October 1, 2000 through September 30, 2001

FUNCTION

The Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases and advises the Commissioner of Food and Drugs of its findings regarding the safety, effectiveness, and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological product licenses, and on the quality and relevance of FDA's research program which provides the scientific support for regulating these agents. The Committee functions at times as a medical device panel under the Medical Device Amendments of 1976.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Committee met two times during the reporting period in Gaithersburg, Maryland. The dates of those meetings were: March 15-16, 2001, and June 14-15, 2001. The meeting on June 14-15, 2001 included a closed session to permit discussion of matters of a personal nature.

ACCOMPLISHMENTS

I. In open session, the March 15-16, 2001 meeting included:

1. The comparative sensitivity of Hepatitis B Virus Nucleic Acid Testing (HBV NAT) vs. Hepatitis B

Surface Antigen (HBsAg) testing. The Committee discussed whether NAT testing for Hepatitis B will be compared with the HBsAg method to determine if blood centers should begin using the NAT testing.

2. The implementation of Nucleic Acid Testing (NAT) for Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV): Testing, Donor and Products Management. The Committee discussion focused on how nucleic acid testing for Hepatitis C and HIV should be implemented.

3. Blood bags for diversion of initial collection. The Committee discussed whether bacterial contamination can be reduced by the use of blood bag diversion pouches.

4. A guidance on Malaria and its applicability to plasma. The Committee discussed whether the guidance for blood donor deferrals for Malaria should be applied to plasma.

II. In open session, the June 14-15, 2001 committee meeting included:

1. Committees updates on: the PHS Advisory Committee on Blood Safety and Availability; current thinking on clinical trial design and performance standards for approval of Rapid HIV Tests; and summaries of FDA workshops.

2. Re-entry for Donors Deferred because of HIV or HCV NAT or Serological Test Results. The Committee continued discussions from the March meeting regarding using additional methodology, such as NAT, for people previously deferred.

3. Clinical Lab Implementation Act (CLIA) Criteria for In Vitro Diagnostic Test: Applicability of Waivers to HIV Rapid Tests. The Committee discussed if CLIA is applicable to HIV rapid tests.

4. Revision of Uniform Donor History Questionnaire. The Committee discussed and heard results from workshops on developing donor questionnaires that are more user friendly.

5. Transfusion-related Acute Lung Injury. The Committee heard a scientific presentation on transfusions that can result in blood clots that may cause lung injury.

6. Studies on Failure of Leukocyte Filtration. The Committee heard results from data collected related to the clogging of filters and associated with source material from sickle cell patients.

In closed session, the Committee recommended personnel and program actions for the Laboratory of Plasma Derivatives, Division of Hematology. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6).

May 8, 2002
Date

Nancy Cherry (for)
Linda A. Smallwood, Ph.D.
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Blood Products Advisory Committee
Center for Biologics Evaluation and Research

Exectutive Secretary

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

ANNUAL REPORT

OF THE

VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

for the period

October 1, 2000 through September 30, 2001

FUNCTION

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met six times during the reporting period. Meetings were held in Bethesda, Maryland and Gaithersburg, Maryland. One meeting was held by teleconference.

The dates of those meetings were November 3, 2000; January 30-31, 2001; March 7-9, 2001; May 16-17, 2001; June 11, 2001; and July 26-27, 2001.

The meetings on March 7-9, 2001, May 16-17, 2001, June 11, 2001, and July 26-27, 2001 included closed sessions to permit discussion of trade secret or confidential commercial information or matters of a personal nature.

ACCOMPLISHMENTS

At the November 3, 2001 meeting:

1. The Committee heard a briefing on the recent Workshop on TSE.

2. The Committee made recommendations pertaining to the safety and efficacy of a PLA for CPDT Adsorbed, a diphtheria/tetanus/acellular pertussis vaccine.

At the January 30-31, 2001 meeting:

1. The Committee discussed and recommended the strains to be included in the influenza virus vaccine for the 2001-2002 season.

2. The Committee reviewed the safety profile for SmithKline Beecham's LYMErix vaccine for Lyme disease including an update of post-marketing safety data.

At the March 7-9, 2001 meeting:

1. In Closed Session, the Committee heard confidential and trade secret information related to manufacturing issues for DTaP-Hepatitis B-IPV.

2. In Open Session, the Committee reviewed safety and immunogenicity data for a combination vaccine, DTaP-Hepatitis B-IPV, manufactured by SmithKline Beecham Biologicals.

3. In four Closed Sessions, the Committee heard confidential and trade secret information related to new pneumococcal conjugate vaccines.

4. In Open Session, the Committee discussed approaches for the approval of new pneumococcal conjugate vaccines.

5. In Open Session, the Committee completed the recommendations, began in January, for the formulation of influenza virus vaccines for 2001-2002.

6. In Open Session, the Committee heard a briefing on activities in the Laboratories of Retrovirus Research and Immunoregulation.

7. In Closed Session, the Committee recommended personnel and program actions for the Laboratory of Retroviruses and the Laboratory of Immunology. Disclosure of the information during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). These recommendations were used by FDA as part of its independent intramural program review.

At the May 16-17, 2001 meeting:

1. In Closed Session, the Committee met to hear a briefing on a manufacturing issues related to use of novel and neoplastic cells as substrates for manufacture of viral vaccines. This session included trade secret or confidential commercial information.

2. In Open Session the Committee discussed adventitious agent testing, tumorigenicity testing, and issues related to residual cell substrate DNA of novel and neoplastic cell substrates used to manufacture viral vaccines.

3. In Closed Session, the Committee met to discuss a product under development. The discussion included trade secret or confidential commercial information.

At the June 11, 2001 meeting:

1. The Committee was briefed on the activities of the Laboratory of Pediatric and Respiratory Viral Diseases.

2. In Closed Session, the Committee recommended personnel and program actions for the Laboratory of Pediatric and Respiratory Viral Diseases. Disclosure of the information during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). These recommendations were used by FDA as part of its independent intramural program review.

At the July 26-27, 2001 meeting:

1. In Closed Session, the Committee was briefed on manufacturing issues related to a product under development. The discussion included trade secret or confidential commercial information.

2. In Open Session, the Committee discussed and made recommendations on the available safety and efficacy data for Aviron Inc.'s cold adapted, live attenuated, trivalent influenza virus vaccine, FluMist) and its proposed indications.

November 16, 2001
Date

Nancy J Cherry
Nancy T. Cherry
Executive Secretary

Vaccines and Related Biological Products Advisory Committee
Center for Biologics Evaluation and Research

Executive Secretary

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANNUAL REPORT
of the
Anti-Infective Drugs Advisory Committee
for the period
October 1, 2000 through September 30, 2001

FUNCTION

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders and make appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETING

The Committee met once during the reporting period in Rockville, Maryland. The date of the meeting was April 26-27, 2001.

The meeting on April 26-27, 2001, included a closed session to permit the presentation of IND/NDA updates and the Catheter-Related Bloodstream Infection Guideline.

ACCOMPLISHMENTS

On April 26, 2001, the Committee met in open session to review new drug application (NDA) 21-144, Ketek® (telithromicyin) tablets, Aventis Pharmaceuticals, Inc., for the treatment of bacterial respiratory infections.

On April 27, 2001, the Committee met in closed session to review presentations of IND/NDA updates for ABT-773, augmentin ES, daptomycin, oritavancin, ramoplanin, ciprodex/moxifloxacin otic preparations, ertapenem/faropenem/E1010 (carbapenems). The Committee also received an update on the Catheter-Related Bloodstream Infection guidance. The Committee's recommendations on these issues remain under discussion.

11-29-01
Date

Thomas H. Perez
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ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE
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DEPARTMENT OF HEALTH & HUMAN SERVICES

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Annual Report of the Arthritis Advisory Committee for the period October 1, 2000 through September 30, 2001

Function

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases, and makes appropriate recommendations to the Commissioner of Food and Drugs.

Membership

A roster of members is attached.

Meetings

The Committee met three times during the reporting period in Rockville, Maryland. The dates of those meetings were: February 7 and 8, 2001, April 19 and 20, 2001, and August 16 and 17, 2001. The meeting on April 20, 2001, and a portion of the meeting on August 17, 2001, were held in closed session to permit the discussion of trade secret and/or confidential commercial information.

Accomplishments

On February 7, 2001, the Committee met to discuss new drug application (NDA) 20-998/S009, Celebrex™ (celecoxib) G.D. Searle & Co., approved for the treatment of signs and symptoms of osteoarthritis and rheumatoid arthritis in adults. The discussion involved appropriateness for modification of the label based on the results of the CLASS Trial, a study of the incidence of significant upper gastrointestinal effects. The Committee recommended the label not be changed. The agency has not amended the label. The Committee met on February 8, 2001, to discuss NDA 21-042/S007, Vioxx™ (rofecoxib) Merck Research Laboratories, approved for the treatment of signs and symptoms of osteoarthritis and the management of acute pain. The discussion involved appropriateness for changes in the product label related to results of the VIGOR Trial concerning clinical

gastrointestinal events. The Committee did not recommend the label be changed. The agency has not modified the label.

The Committee met on April 19, 2001, to discuss NDA 21-239, Aslera® (prasterone) Genelabs Technologies, Inc., for improvement in disease activity and/or its symptoms in women with mild to moderate Systemic Lupus Erythematosis (SLE) and reduction of corticosteroid requirement in women with mild to moderate SLE. The Committee did not recommend approval of the product and the agency has not approved it. The Committee met on April 20, 2001, in closed session.

The Committee met on August 16, 2001, to discuss the safety and efficacy of BLA 103950 Kineret™ (anakinra) Amgen, Inc., for reduction in signs and symptoms of active rheumatoid arthritis. The Committee had several recommendations for further study and agreed that the product is effective. The Center for Biologics Evaluation and Research has not yet taken action. A portion of the August 17, 2001, meeting was closed. The open portion of the August 17, 2001, meeting was a presentation and discussion of safety updates, postmarketing studies for Enbrel™ (etanercept) Immunex, and Remicade™ (infliximab) Centocor, for the treatment of rheumatoid arthritis.

12/6/01
Date

Kathleen Reedy
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January, 2001

Food and Drug Administration
Rockville MD 20857

ANNUAL REPORT

OF THE

Cardiovascular and Renal Drugs Advisory Committee
for the period

October 1, 2000 through September 30, 2001

FUNCTION

The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for the treatment of cardiovascular and renal disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

See List below

MEETINGS

The committee met 3 times during the reporting period in Bethesda, Maryland.

The dates of those meetings were October 19 and 20, 2000, May 24 and 25, 2001, and August 9 and 10, 2001. The meeting of October 19 was held in closed session to permit the discussion of trade secret and/or confidential commercial information.

ACCOMPLISHMENTS

The committee met on October 19 and 20, 2000. On October 19, 2000, the committee discussed trade secret/confidential information. On the October 20, 2001, the committee discussed dose response using data from approved antihypertensive drugs.

On May 24, 2001, the committee discussed (1) published interim analyses of ALLHAT (antihypertensive and lipid lowering treatment to prevent heart attack trial) sponsored by the National Heart, Lung, and Blood Institute, National Institutes of Health; and (2) Response to the Citizen's Petition of Lawrence D. Bernhardt and Arnold Liebman, regarding new drug application (NDA) 19-668, Cardura (doxazosin), Pfizer Inc. On May 25, 2001, the committee discussed NDA 20-920, Natrecor (nesiritide), Scios Inc., indicated for the treatment of acute heart failure. The committee voted unanimous for approval.

On August 9 and 10, 2001, the committee discussed NDA 21-272, Remodulin, (treprostinil sodium), United Therapeutics, for the treatment of pulmonary hypertension; NDA 21-321, Extraneal, (7.5% icodextrin), Baxter Healthcare, for chronic renal failure; NDA 21-290, Tracleer, (bosentan), Actelion, for the treatment of pulmonary hypertension. The three drugs were recommended for approval.

5/1/02
Date

Jaime Henriquez for
Jaime Henriquez
Executive Secretary

ROSTER of the Cardiovascular and Renal Drugs Advisory Committee
For the reporting period 10/1/00 – 9/30/01

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANNUAL REPORT

OF THE
Dermatologic and Ophthalmic Drugs Advisory Committee

for the period

October 1, 2000 through September 30, 2001

FUNCTION

The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met one time during the reporting period in the Washington, DC area.

The date of the meeting was November 16, 2000.

The meeting on November 16, 2000 included a closed session to permit discussion of trade secret or confidential commercial information.

ACCOMPLISHMENTS

On November 16, 2000, the committee discussed NDA 50 – 777, Protopic, tacrolimus, Fujisawa Healthcare, for short and long term treatment of the signs and symptoms of atopic dermatitis in adult and pediatric patients 2 years of age or older. The committee voted for the approval of Protopic.

5/1/02
Date

Jaime Peterson for
Jaime Henriquez

Executive Secretary

DERMATOLOGIC AND OPHTHALMIC DRUGS ADVISORY COMMITTEE

CHAIRMAN

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Rockville MD 20857

ANNUAL REPORT

of the

ONCOLOGIC DRUGS ADVISORY COMMITTEE

for the period

October 1, 2000 through September 30, 2001

FUNCTION

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and makes appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Committee met five times during the reporting period in Bethesda and Rockville, Maryland. The dates of those meetings were December 13 and 14, 2000, April 28, 2001, June 7, 2001, June 28, 2001 and September 10 and 11, 2001. Part of the meeting on June 7, 2001 was held in closed session to permit the discussion of trade secret and/or confidential commercial information.

ACCOMPLISHMENTS

On the morning of December 13, 2000, the Committee met to discuss NDA 20-726/S006, Femara® (letrozole) Tablets, Novartis Pharmaceuticals Corporation, indicated for first-line therapy in postmenopausal women with advanced breast cancer. The Committee agreed that the studies showed that Femara was at least equivalent to tamoxifen as the initial hormonal treatment of postmenopausal women with hormone receptor positive or hormone receptor unknown advanced metastatic breast cancer, with a median of 3.6 months improvement in median time to tumor progression. Clinical experience shows that the aromatase inhibitors are safe and well-tolerated, and the Committee indicated that

these data suggest that standards of care may shift to choosing this drug class for first-line treatment of advanced breast cancer in postmenopausal women. They voted 13-0 that the supplement was approvable and an approval letter was sent on January 10, 2001.
Also on December 13, 2000, the Committee heard presentations regarding NDA 21-240, histamine hydrochloride injection (1 mg/ml, Maxim Pharmaceuticals, Inc., indicated for the adjunctive use with interleukin-2 (aldesleukin) in the treatment of adult patients with advanced metastatic melanoma that has metastasized to the liver. The Committee expressed serious concerns about the number of imbalances in the design of this single study, which did not include stratification by prognostic factors, or by presence of liver metastases at study entry. In the intent-to-treat population, survival differences were not statistically significant and there was no internal consistency across subgroups. Although significant survival differences were found in the liver metastasis subgroup, imbalances in the prognostic factors consistently favored the histamine/IL2 arm and, when calculations were adjusted for these imbalances, there was no significant survival difference between the two treatments. The Committee voted 14-0 against approval.
On the morning of December 14, 2000, the Committee met to discuss BLA 99-0786, Campath®, (alemtuzumab), Millenium and ILEX Partners, LP, indicated for the treatment of patients with chronic lymphocytic leukemia who have been treated with alkylating agents and who have failed fludarabine therapy. The Committee indicated that the infusion and hematologic toxicities and the high frequency of infections were not serious concerns because, with our increasing experience with monoclonal antibodies, those toxicities can be anticipated and prophylactic measures taken. The Committee was concerned about the 13% treatment-related mortality and suggested that CAMPATH should not be used as palliative care in patients with a good prognosis. The need for a Phase III commitment was stressed, with the goal of also refining dosing information so that patients are exposed to the minimum effective dose for their tumor burden. The Committee voted 14-1 in favor of accelerated approval and an approval letter was issued on May 7, 2001. On the afternoon of December 14, 2001, the Committee heard presentations on the Single Patient Use of Non-approved Oncology Drugs and Biologics. Due to lack of time, the discussion of the Questions to the Committee was tabled to the next meeting of the ODAC.

On April 28, 2001, the Pediatric Subcommittee of the Oncologic Drugs Advisory committee met to provide advice to the FDA on the cases in which pediatric hematological malignancies may be considered to be the same indication as adult malignancies. The Subcommittee highlighted the need for cooperation, ethical studies, and prioritization of potential studies, and indicated that for vaccine development, shared surface antigens may provide sufficient basis for doing both adult and pediatric studies.

On June 7, 2001, the Committee met to continue the discussion of the Single Patient Use of Non-approved Oncology Drugs and Biologics. The committee discussed ways to educate the public on this important topic and provided advice on when the FDA should allow treatment use.

On June 28, 2001, the Pediatric Subcommittee of the Oncologic Drugs Advisory committee met to provide advice to the FDA on when pediatric solid tumors and CNS malignancies may be considered to be the same indication as adult malignancies.

On the morning of September 10, 2001, the Committee discussed Clinical Trial Designs for the First-line Hormonal Treatment of Metastatic Breast Cancer . Topics covered included discussions about the comparators, clinical trial design, endpoints and standards of eficacy. On the afternoon of September 10, 2001, the Committeee discussed NDA 21-236, IntraDose® (cisplatin/epinephrine) Injectable Gel, Matrix Pharmaceuticals, Inc., indicated for the treatment of recurrent or refractory squamous cell carcinoma of the head and neck in patients who are not considered curable with surgery or radiotherapy . The Committee noted that the trials showed definite anti-tumor activity of the drug, although clinical benefit was not demonstrated. They expressed concern about the safety of the treatment, especially in treating tumors of the neck of patients with prior surgeries. They voted 4-9 against approval (1 abstention).

On the morning of September 11, 2001, the Committee considered BLA 125019, Zevalin™ (ibritumomab tiuxetan), IDEC Pharmaceuticals Corporation, indicated for the treatment of patients with relapsed or refractory low grade, follicular or CD20+ transformed B cell Non-Hodgkins lymphoma (NHL) and rituximab refractory follicular NHL. The Committee unanimously recommended (1 abstention) approval of Zelvalin for the treatment of chemotherapy and Rituxan-refractory patients, but voted against recommending Zevalin as an initial therapy because of toxicities that accompany its benefits. Also on September 11, 2001, the Committee was scheduled to discuss NDA 20-637/S016, Gliadel® Wafer (carmustine), Guilford Pharmaceuticals Inc., indicated for use as a treatment to significantly prolong survival and maintain overall function (as measured by preservation of Karnovsky Perfomance Status) and neurological function in patients with malignant glioma undergoing primary and/or recurrent surgical resection. However, due to the national emergency, this last session was canceled. It will be rescheduled for a later date.

11/21/01
Date

Karen M. Templeton-Somers, Ph.D.
Executive Secretary

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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ANNUAL REPORT

OF THE

MEDICAL DEVICES ADVISORY COMMITTEE

for the period

October 1, 2000 through September 30, 2001

Function

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions the FFDC Act envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises the Commissioner of Food and Drugs regarding recommended classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the Act; advises on the necessity to ban a device; and responds to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner of Food and Drugs on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between the FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The Panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

MEETINGS

The Medical Devices Advisory Committee held 23 meetings during the reporting period in Gaithersburg, Maryland; Rockville, Maryland; and Silver Spring, Maryland.

Below are the dates of all device panel meetings during FY 2001 (10/1/00 to 9/30/01) and UNDERLINED dates represent meetings that had closed sessions:

10/6/00	Dental Products Panel
10/19/00	Gastroenterology and Urology Devices Panel
10/31/00	Medical Devices Dispute Resolution Panel
11/6/00	Radiological Devices Panel
11/8/00	Ophthalmic Devices Panel
11/13-14/00	Clinical Chemistry and Clinical Toxicology Devices Panel
11/16/00	Neurological Devices Panel
12/4-5/00	Circulatory System Devices Panel
12/8/00	Microbiology Devices Panel
1/19/01	Orthopaedic and Rehabilitation Devices Panel
1/29/01	Obstetrics and Gynecology Devices Panel
2/5/01	Circulatory System Devices Panel
3/5/01	Radiological Devices Panel
4/23/01	Circulatory System Devices Panel
5/21-22/01	Obstetrics and Gynecology Devices Panel
7/9-10/01	Circulatory System Devices Panel
7/16/01	Anesthesiology and Respiratory Therapy Devices Panel
7/17/01	General and Plastic Surgery Devices Panel
7/20/01	Ophthalmic Devices Panel
8/8-9/01	Orthopaedic and Rehabilitation Devices Panel
8/17/01	Gastroenterology and Urology Devices Panel
9/6/01	Medical Devices Dispute Resolution Panel
9/10-11/01	Circulatory System Devices Panel

ACCOMPLISHMENTS

See attachments (accomplishments are reported for 10 panels).

ANESTHESIOLOGY AND RESPIRATORY THERAPY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met once during the reporting period in Rockville, Maryland.

The date of the meeting was July 16, 2001.

The meeting on July 16, 2001, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding pending and future anesthesiology and respiratory therapy device submissions.

ACCOMPLISHMENTS

During the July 16, 2001 meeting, a premarket approval application (PMA) supplement from SensorMedics Corporation for the 3100 High Frequency Oscillator Ventilator (HFOV), which is used to treat acute respiratory insufficiency in adults, was recommended for approval with one condition related to labeling change.

November 16, 2001
Date

for Kathleen Walker
Michael G. Bazaral, M.D.
Executive Secretary

WORK ADDRESS ROSTER
SORTED BY PANEL/COMMITTEE, FUNCTION, NAME

ANESTHESIOLOGY AND RESPIRATORY THERAPY DEVICES PANEL

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ANESTHESIOLOGY AND RESPIRATORY THERAPY DEVICES PANEL

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ANESTHESIOLOGY AND RESPIRATORY THERAPY DEVICES PANEL

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11/30/01

CIRCULATORY SYSTEM DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met five times during the reporting period in Gaithersburg, Maryland; and Silver Spring, Maryland.

The dates of the meetings were December 4 and 5, 2000, February 5, 2001, April 23, 2001, July 9 and 10, 2001 and September 9 and 10, 2001.

The meeting on February 5, 2001 included a closed session to permit discussion and review of trade secret and/or confidential commercial information. This portion of the meeting was closed to permit discussion of pending and future circulatory system device submissions. In addition, the committee discussed and reviewed trade secret and/or confidential commercial information presented by a sponsor.

ACCOMPLISHMENTS

During the February 5, 2001 meeting, the panel discussed PercuSurge, Inc.'s premarket notification (510(k)) submission for the Percusurge Guardwire Plus® Temporary Occlusion and Aspiration System. The panel determined that the benefits of the product outweighed the risks. This distal device is indicated for use in diseased coronary saphenous vein bypass grafts to contain and aspirate embolic material while performing percutaneous transluminal coronary angioplasty and stenting procedures or to locally infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion. The panelists also discussed clinical study design issues for distal protection devices used in the treatment of saphenous vein graft disease. Following public presentations, the panel addressed questions posed by the FDA.

November 16, 2001
Date

Kathleen Walker for Megan Moynahan
Executive Secretary

WORK ADDRESS ROSTER
SORTED BY PANEL/COMMITTEE, FUNCTION, NAME

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CIRCULATORY SYSTEM DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

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CLINICAL CHEMISTRY and CLINICAL TOXICOLOGY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met once during the reporting period in Gaithersburg, Maryland.

The date of the meeting was November 13- 14, 2000.

The meeting on November 14, 2000 included a closed session to permit discussion and review of trade secret and/or confidential commercial information regarding pending and future FDA issues.

ACCOMPLISHMENTS

During the November 13-14, 2000 meeting, on the first day, the panel discussed two guidance documents: "Guidance for Prescription Use Drugs of Abuse Assays Premarket Notification" and "Over the Counter (OTC) Screening Tests for Drugs of Abuse (DOA): Guidance for Premarket Notifications." The panel provided recommendations on study designs and established cutoffs for the prescription use DOA 510(k)s. In reference to the OTC DOA 510(k)s, the panel provided recommendations on mandatory confirmation testing, appropriateness of proposed studies and labeling, applicability to OTC alcohol testing and cutoff performance.

On the second day, the panel discussed Psychemedics Corporation's 510(k) submission for the Psychemedics Analysis of Morphine in Hair. The panel was not asked to vote on the application, but answered questions posed by the FDA. This first of a kind opiate radioimmunoassay device is intended for the qualitative and semi-quantitative analysis of heroin in human hair with a cutoff at 2 ng/10mg hair.

November 16, 2001
Date

for Veronica J. Calvin
Executive Secretary

WORK ADDRESS ROSTER
SORTED BY PANEL/COMMITTEE, FUNCTION, NAME

CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

EXECUTIVE SECRETARY

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CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

NONVOTING MEMBERS

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DENTAL PRODUCTS PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met once during the reporting period in Rockville, Maryland.

The date of the meeting was October 6, 2000.

The meeting on October 6, 2000, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding dental device issues.

ACCOMPLISHMENTS

On October 6, 2000, the panel deliberated on a PMA presented by TMJ Implants, Inc. for the Fossa-Eminence Prosthesis. This is a partial temporomandibular joint implant intended to reconstruct a smooth temporal bone surface for articulation of the natural condyle. The panel recommended that this pre-amendment device be found not approvable. They also provided the sponsor with the requirements for placing the PMA in approvable form. At the same meeting the committee discussed and made recommendations on the labeling for TMJ Concepts's total TMJ prosthesis.

November 16, 2001
Date

for Pamela D. Scott
Executive Secretary

DENTAL PRODUCTS PANEL OF THE MEDICAL DEVICE ADVISORY COMMITTEE

EXECUTIVE SECRETARY

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NONVOTING MEMBERS

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GENERAL AND PLASTIC SURGERY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met once during the reporting period in Gaithersburg, Maryland.

The date of the meeting was July 17, 2001.

The meeting on July 17, 2001, included a closed session to permit discussion of trade secret and/or confidential information relating to pending issues and applications.

ACCOMPLISHMENTS

On July 17, 2001, the panel discussed a PMA sponsored by Ortec International for OrCel™ Composite Cultured Skin. The panel voted unanimously in favor of approval with conditions. The conditions included further histological evaluation and labeling modifications. The device is indicated for the management of split thickness donor sites in burn patients and consists of crosslinked Type I bovine collagen on either side of which human neonatal foreskin fibroblasts and keratinocytes are seeded and cultured.

November 16, 2001
Date

for David Krause, Ph.D.
Executive Secretary

WORK ADDRESS ROSTER
SORTED BY PANEL/COMMITTEE, FUNCTION, NAME

GENERAL AND PLASTIC SURGERY DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

EXECUTIVE SECRETARY

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NEUROLOGICAL DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met once during the reporting period in Rockville, Maryland.

The date of the meeting was November 16, 2000.

The meeting on November 16, 2000, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding pending issues and applications.

ACCOMPLISHMENTS

On November 16, 2000, the panel made recommendations on: (1) the design of clinical trials for new devices to prevent stroke, to treat stroke, and to provide neurological protection after stroke; and (2) the design of clinical studies for temperature control devices to provide neurological protection.

November 16, 2001
Date

for Janet L. Scudiero
Executive Secretary

WORK ADDRESS ROSTER
SORTED BY PANEL/COMMITTEE, FUNCTION, NAME

NEUROLOGICAL DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

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11/30/04

OBSTETRICS and GYNECOLOGY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met two times during the reporting period in Gaithersburg, Maryland.

The dates of the meetings were January 29, 2001 and May 21 and 22, 2001.

The meeting on January 29, 2001, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding pending and future device issues. The meeting on May 22, 2001, included a closed session in order for the panel to discuss and review trade secret and/or confidential commercial information presented by a sponsor.

ACCOMPLISHMENTS

On January 29, 2001, the panel discussed Cryogen, Inc.'s PMA for the FirstOption™ Therapy System intended for endometrial ablation in women with abnormal uterine bleeding in whom childbearing is complete. Following the deliberations, the panel recommended approval with conditions related to device malfunction rate, labeling, and standardization of technique.

During the May 21 and 22, 2001 meeting, during the first day, the panel discussed a PMA supplement from Mallinckrodt, Inc. for the OxiFirst® Fetal Oxygen Saturation Monitoring System. The device continuously monitors intrapartum fetal oxygen saturation ($FsPO_2$) and is indicated for use as an adjunct to fetal heart rate (FHR) monitoring in the presence of a non-reassuring heart rate pattern. The panel provided comments on three proposed studies and urged that the studies be conducted as soon as possible. On the same day, the panel heard a presentation by Novatrix, Inc. on the regulatory process and clinical findings for a labor assist system. The company will not pursue PMA approval.

On the second day, The panel discussed issues concerning air and gas emboli associated with operative hysteroscopy. The panel concluded that additional research is needed to further understand the risk and that good clinical practice is essential for minimizing risk. In addition, the panel recommended mechanisms for heightening clinical awareness of risk. On the same day, the committee discussed issues concerning uterine fibroid embolization in order to assist FDA in its development of product applications and guidance documents. The panel provided comments on inclusion and exclusion criteria, study endpoints, length of follow-up, re-treatment, and labeling.

November 16, 2001
Date

for Kathleen Walker
Joyce M. Whang
Executive Secretary

WORK ADDRESS ROSTER
SORTED BY PANEL/COMMITTEE, FUNCTION, NAME

OBSTETRICS AND GYNECOLOGY DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

EXECUTIVE SECRETARY

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WORK ADDRESS ROSTER
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OBSTETRICS AND GYNECOLOGY DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

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OPHTHALMIC DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met twice during the reporting period in Rockville, Maryland and Gaithersburg, Maryland.

The dates of the meetings were November 8, 2000 and July 20, 2001.

The meeting on July 20, 2001, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding pending issues and applications.

ACCOMPLISHMENTS

On July 20, 2001, a PMA presented by Ciba Vision Corporation for the Focus®Night and Day™ (lotrafilconA) soft contact lens was recommended for approval with conditions. The conditions include modifications to the indication statement and to the labeling, and a post approval requirement. The device is indicated for the optical correction of refractive ametropia in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters of astigmatism. The lenses may be prescribed for extended wear for up to 30 nights of continuous wear between removals for cleaning and disinfection or for disposal of the lens, as recommended by the eye care professional.

November 16, 2001
Date

for Kathleen L Walker
Sara M. Thornton
Executive Secretary

WORK ADDRESS ROSTER
SORTED BY PANEL/COMMITTEE, FUNCTION, NAME

OPHTHALMIC DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE

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ORTHOPAEDIC and REHABILITATION DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met two times during the reporting period in Rockville, Maryland and Gaithersburg, Maryland.

The dates of the meetings were January 19, 2001 and August 8 and 9, 2001.

The meeting on August 8, 2001, included a closed session to permit FDA to present to the committee trade secret and/or confidential commercial information regarding present and future FDA issues.

ACCOMPLISHMENTS

During the August 8-9, 2001 meeting, on the first day, the panel recommended that class III 510(k) metal-on- metal semi-constrained total hip joint prostheses devices not be reclassified into class II 510(k). They believed that the petitioner did not provide adequate clinical data to support the reclassification. In addition, the panel had concerns regarding the use of wear testing: (1) what to use as a control (negative or positive or both); and (2) what the wear results would mean regarding clinical performance.

On the second day, a PMA presented by Ascension Orhopedics, Inc. for the Ascension® MCP finger joint prosthesis was recommended for approval with conditions. The conditions included (1) narrowing the indications for use; (2) specific onsite training; (3) caution regarding use in the small/ring finger; and (4) contraindications for severe deformity in rheumatoid arthritis. The device is a semi-constrained total joint replacement for the index, long, ring, and small finger metacarpophalangeal joints.

November 16, 2001
Date

for Kathleen Walker
Hany W. Demian
Executive Secretary

WORK ADDRESS ROSTER
SORTED BY PANEL/COMMITTEE, FUNCTION, NAME

ORTHOPAEDIC AND REHABILITATION DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

EXECUTIVE SECRETARY

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RADIOLOGICAL DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met two times during the reporting period in Rockville, Maryland.

The dates of the meetings were November 6, 2000 and March 5, 2001.

The meeting on November 6, 2000, included a closed session to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future agency issues.

ACCOMPLISHMENTS

On November 6, 2000, a PMA for SIR-Spheres®, presented by SIRTex Medical Limited of Australia, was recommended for approval with conditions. Two conditions were proposed: labeling changes and the indication for use should be for treatment of metastatic colorectal cancer. If the FDA receives other information on primary or secondary cancer treatment, they should move aggressively to pursue such information; therefore, a post-approval study of safety and effectiveness should be designed with the FDA to include the use of new systemic chemotherapy agents. This embolic radiation therapy device is intended to selectively deliver high doses of ionizing radiation through ^{90}yttrium phosphate-coated microspheres that are implanted into non-operable malignant liver tumors.

November 16, 2001
Date

for Kathleen Walker
Robert J. Doyle
Executive Secretary

WORK ADDRESS ROSTER
SORTED BY PANEL/COMMITTEE, FUNCTION, NAME

RADIOLOGICAL DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

EXECUTIVE SECRETARY

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANNUAL REPORT

OF THE
SCIENCE ADVISORY BOARD TO THE
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

for the period

October 1, 2000 through September 30, 2001

FUNCTION

The Board advises the Director, NCTR, in establishing, implementing and evaluating the research programs that assist the Commissioner of Food and Drugs in fulfilling his/her regulatory responsibilities. The Board provides an extra-agency review in ensuring that the research programs at NCTR are scientifically sound and pertinent.

MEMBERSHIP

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MEETINGS

The committee met one time during the reporting period in Jefferson, Arkansas.

The date of the meeting was June 11/12, 2001.

The meeting on June 12, 2001 included a closed session to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The Board discussed qualifications and performance of individuals associated with the research programs at the Center that had undergone review.

ACCOMPLISHMENTS

The Board received progress reports on the implementation of recommendations made by the Board at its last meeting from the Endocrine Disrupter Knowledge Base, and Microbiology program directors. They addressed the issues raised and actions taken on the recommendations made in the program review reports.

A proposal was made to the Board that it consider establishing a subcommittee on scientific opportunities to improve regulatory science through collaborations with external stakeholders. A report will be provided to the Board on the activities of an existing subcommittee with a similar focus (Advisory Committee for Pharmaceutical Science, Nonclinical Studies Subcommittee). The Board postponed making a decision pending further evaluation of the information provided.

The NCTR division directors discussed the accomplishments and future directions for their divisions.

Date: 12-7-01

Leonard M. Schechtman, Ph.D.
Executive Secretary